REMARKS

Examiner Kennedy is thanked for withdrawing the finality of the previous action, and reconsidering the claims as amended. However, the present Office Action rejects the claims over two previously unidentified references. Further consideration of the claims and withdrawal of the pending rejections is respectfully requested.

Claims 2-4, 6-7 and 9-27 are Not Obvious over Guala and Johnson

The present Office Action offered for the first time U.S. Patent Nos. 5,611,576 to Guala and 5,702,374 to Johnson, and alleged that the claims were obvious over Guala in view of Johnson. Respectfully, these references would not have made the claimed subject matter obvious to one of ordinary skill in this art, and therefore withdrawal of this rejection is requested.

"[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385, 1396 (2007). Rather, an explicit analysis concerning alleged obviousness is required, and it is important "to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *Id.* A principal focus of the non-obviousness question is whether the result of the combination would have been predictable at the time the invention was made to one of ordinary skill, or whether there was a reasonable expectation of success in making the combination.

One of ordinary skill starting with the information in Guala would not expect a successful result from incorporating the external surface 25 from Johnson onto the outside of Guala's item 6. Guala teaches a female luer connector which has two parts, an internal part 6 that accepts a male luer connector (described but not shown in the reference) and an external part 2. Guala teaches a hard plastic for item 2 and a soft material for item 6 (column 2, lines 1-4), and a close agreement

between the outer diameter of item 6 and the inner diameter of item 2 (see Guala's Figure). Its identified advantage is the ability of item 2 to turn around item 6, as compared to similar items locked together by projections on the inner sleeve extending through apertures (col. 1, lines 22-25).

Johnson's item 25 is a "distal section . . . which is generally tubular shaped with little taper" (col. 2, lines 53-54). In other Figures, item 25 does not have a taper, while in Figure 5 it starts from an outer cylindrical diameter of item 12/112, extending outward and abutting "lock nut receiving section 24" of the same outer cylindrical diameter of item 12/112. Thus, to the extent Johnson section 25 has any taper, it widens from the otherwise uniform outer diameter of item 12/112 to a maximum diameter, then steps back down to the uniform outer diameter at part 24a.

One of ordinary skill cannot expect success in combining Guala and Johnson as the Office Action has done. Guala's goal is to allow rotation of its hard item 2 about its soft cylindrical item 6. Widening item 6 from its uniform outer diameter to a larger maximum diameter, as Johnson teaches, creates a mass of soft material on the outside of item 6 forced against the inner diameter of item 2. One of ordinary skill would see two potential results occurring. First, forcing the mass of soft material against the hard interior would create substantial friction, impeding or preventing turning of item 2 with respect to item 6. If item 2 can be turned around item 6, the friction will grip, abrade or weaken the soft material of item 6. Gripping friction tends to move item 6 along with item 2, which is the principal result Guala teaches to avoid. Guala teaches to avoid locking an outer body to an inner sleeve with the resulting potential for damage or failure (column 1, lines 21-32). Increasing grip between items 2 and 6 is the opposite of Guala's disclosure.

The second possible result is that the hard plastic item 2 forces the mass of soft material into an approximately cylindrical exterior that conforms to the inner diameter of item 2, simultaneously creating a bulge of soft material into the lumen of item 6 that distorts the precise

conic shape of the lumen of item 6. In that case, the insertion of a male luer connector will be blocked or impeded. A fluid-tight taper-lock connection would be made less likely because the male luer connector cannot be inserted as far as is needed for a fluid-tight connection. Of course, if the male luer connector is forced against the soft bulge inside item 6, the likelihood of a tear or weakness in the bulge increases, along with the likelihood of leakage. Such a bulge decreases the area through which fluid flows, increasing pressure on the luer members and/or reducing efficiency in transferring fluid through the connection as well.

Moreover, the references' goals are opposed to each other. As noted above, Guala teaches that twisting force generated by turning item 2 with respect to item 6 is to be avoided (column 1, lines 21-32). Guala's objective is to provide parts that rotate with respect to each other around an axis, without binding or twisting each other. Johnson, on the contrary, focuses on locking to prevent relative twisting or turning of its parts. Johnson teaches a locking ring 16 that firmly and unrotatably fits on a male luer connector via engagement of teeth 42 and 23a, and also prevents rotation between itself and lock nut 14 via engagement of teeth 46 and 35a. When assembled as in Fig. 3, items 14, 16 and 12 are prevented from turning with respect to each other, accomplishing the goal of preventing twisting and loosening among these parts (see, e.g., column 1, lines 25-31).

Johnson additionally directs one of ordinary skill away from placing its surface 25 inside a locking nut, at least implicitly, because of its placement of its locking ring inside its locking nut. Johnson teaches preventing loosening of its nut 14 with respect to its male luer member by locking the nut and the luer member together via internal locking ring 16. One of ordinary skill can see that Johnson's surface 25 must remain outside nut 14, or it would interfere with the action of locking ring 16, which is the crucial part in Johnson's way of holding nut 14 and luer member 12 together.

Consequently, one of ordinary skill in this art could see no reasonable expectation of success in combining the outwardly-bulging surface 25 as taught by Johnson with the female luer connector as taught by Guala, and further the disclosures of each reference aim for opposed objectives. If the teachings of Johnson are applied to Guala's item 6, against Guala's own directions, an ineffective device is expected by one of ordinary skill. Further, one familiar with luer connectors sees from the beginning that Johnson teaches prevention of turning of a lock with respect to a male luer connector, while Guala instructs that turning of those pieces with respect to each other is its principal goal. This is not a case of equivalent structure or principle being transferred to another device with predictable results. Even if all of the pieces of the present claims are discoverable in these references, the underlying technical bases in the references show no reason for one of ordinary skill in the art to combine them, as is required by *KSR*.

It is also noted that not all elements of the claims are found in the references. For example, with due respect the Guala reference does not show a "one-piece locking member" as recited. Rather, Guala identifies that two pieces lock its item 6 with a male luer connector. At column 2, lines 28-35, Guala explains that a male luer connector with some internally-threaded member is connected to Guala's item 1. The male luer connector is inserted into item 6, and its associated internally-threaded member threads onto thread 5 of item 2. The connection between the male luer connector and item 6 is thus locked with two pieces, item 2 and the threaded item associated with the male luer connector.

The remaining claims in this rejection are dependent from claim 11 or claim 14, and are thus also allowable on that basis and/or on their own merit. For example, claim 2 recites that the locking member comprises a finlike handle. The Office Action suggested that Guala shows a

"finlike" handle, but there is no textual disclosure of such a handle. Guala's cross-sectional drawing shows at best two rectangular flats extending from the side of its item 2.

Likewise, Guala's figure does not show an undulating grip of a locking member, as recited in claim 3. The cross-sectional drawing does not include enough information to determine whether a grip surface of item 2 undulates. In particular, the regions 4 suggest only a flat rectangular extension visible behind the hatched "cut" of the cross-section. No information is given in the drawing or specification about the configuration of that surface, or of any other unseen part of item 2.

As to claim 4, Figure 9 of this application shows an example of a skeletal handle (see also paragraphs 46-47), and the specification differentiates between a skeletal handle and other types of handles (see, e.g., paragraphs 61-64). With due respect, "skeletal handle" is a proper structural limitation, which is not found in the Guala or Johnson references. The Office Action merely brushes off this limitation without considering its meaning, either an "ordinary" meaning or what the specification might say about it. It is incumbent upon the Examiner to consider all limitations and to find corresponding structure in cited references, and the mere allegation that a "skeletal handle" does not provide structure is not a sufficient analysis, and is not borne out by the claim language and specification.

As with claims 2 and 3, neither Guala nor Johnson show enough information for one to determine that their respective items 2 and 14 have an indentation approximating the shape of a human thumbprint, as recited in claim 6. Guala's cross-sectional figure does not have any information of what shape or size the areas between its rectangular flats 4 might be. Johnson's Figure 1 shows only a cylindrical surface between longitudinal splines. There is no disclosure in Johnson's drawings or specification such a cylindrical surface might represent a thumbprint.

As to claims 9 and 10, the above remarks establish that they are not shown or suggested by Guala or Johnson. Moreover, nothing in those references shows or suggests a combination of handle types or configurations on one locking member. Again, since Guala's item 2 is only shown in cross-sectional view and Johnson's item 14 is only disclosed as a cylinder, there is insufficient information to establish the features of claims 9 and 10 in the cited references.

Claims 15-20 depend from independent claim 14, and are not shown or suggested by Guala and Johnson on that basis and/or on their own merit. For example, claims 17-19 recite examples of handles shown in the present application. As discussed above, neither Guala nor Johnson include enough information to show or suggest those structures.

Claim 8 is Not Obvious over Peters With or Without Werschmidt

The Office Action alleged claim 8 to be obvious over Guala (without Johnson) in view of the previously-cited Werschmidt reference. This rejection cannot stand because neither Guala nor Werschmidt show at least the conical restraining surface recited in claim 11, from which claim 8 depends. Since the combination of references (Guala and Werschmidt) does not show all elements of claim 8, this rejection should be withdrawn.

With due respect to the Examiner, several Office Actions in this case have now cited to the Werschmidt reference without citing any part of Werschmidt for any particular disclosure, much less the particular configuration of claim 8. The present Office Action once again made no reference at all to Werschmidt at all other than citing its number.

As noted above, Guala does not show all features of independent claim 11, nor does it show an undulating grip. The continuing lack of any citation to specific portions of Werschmidt,

as required to support this putative rejection, shows that a *prima facie* basis for the rejection has not been made.

Moreover, the Office Action's refusal to say what part of Werschmidt is at issue means that Applicants cannot make an efficient, focused response, since it is not known what aspects of that reference are relied on by the Office Action. It is noted that Figures 1 and 2 of Werschmidt do not disclose the features of claim 11 (or claim 8) missing from Guala. The allegation that Guala does not disclose any structural or functional significance to the number of undulations (per the Office Action) indicates a lack of disclosure in Guala, not a state of mind of one of ordinary skill in the art as to a number of undulations. There is no evidence in the record to support the Office Action's conclusion that the subject matter of claim 8 is (1) merely a change in shape or (2) that it would yield expected and predictable results.

The Section 112 Rejection Should Be Withdrawn

The rejection of claims 2, 7, 10 and 17 as allegedly indefinite in using the term "finlike" was continued. Applicants thank Examiner Kennedy for withdrawing his reliance on MPEP 2173.05(d) in this rejection, and respectfully maintain that the principles in MPEP 2173.05(b) also do not support this rejection.

As noted before, the test for definiteness is whether a claim is "insolubly ambiguous without a discernable meaning after all reasonable attempts at construction." *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1366, 71 USPQ2d 1081, 1089 (Fed. Cir. 2004), *cited in* MPEP 2173.02. The MPEP notes that the claim language must be analyzed in light of the specification. *Id.* A "claim term that is not used or defined in the specification is not indefinite if the meaning of the claim term is discernible." *Id.* (*citing Bancorp Svcs., LLC v.*

Hartford Life Ins. Co., 359 F.3d 1367, 1372, 69 USPQ2d 1996, 1999-2000 (Fed. Cir. 2004)). Moreover, the Federal Circuit has instructed that the standard for definiteness is "[i]f one skilled in the art would understand the bounds of the claim when read in light of the specification, then the claim satisfies section 112 paragraph 2. *Exxon Res. & Eng'g. Co. v. United States*, 60 USPQ2d 1272, 1276 (Fed. Cir. 2001). "We have not insisted that claims be plain on their face in order to avoid condemnation for indefiniteness; rather, what we have asked is that the claims be amenable to construction, however difficult that task may be. If a claim is insolubly ambiguous, and no narrowing construction can properly be adopted, we have held the claim indefinite. If the meaning of the claim is discernible, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree, we have held the claim sufficiently clear to avoid invalidity on indefiniteness grounds." *Id.*

The Office Action's discussion (pages 9-11) about "finlike" and how it is used in the specification points out why the claims using it are definite. In response to the Examiner's views, the following points are offered:

1) "Finlike" is used throughout the specification, and it is used to refer to the embodiment labeled 122, 124 in Figure 10 of the application. The positioning of the use of that term and discussion of exemplary structure in the specification is irrelevant. One of ordinary skill reading the specification sees the term "finlike" and associates it with exemplary structure.

2) The Examiner is correct that "finlike" is used by itself as well as with the term "solid" in the specification. As the Examiner suggests, this gives the person of ordinary skill more information about "finlike," as it indicates that "finlike" is independent of solidity or hollowness. This language makes the boundary of "finlike" sharper as well as broader.

3) Likewise, the disclosure that the shape may be that of a dorsal fin is one example of subject matter within the meaning of "finlike." Once again, the association of the term in question with a particular example makes the term more definite, not less definite.

4) The specification provides examples of structures and shapes that are within the scope of "finlike." The definition of a term can readily be determined by ordinary meaning, context in the specification and reference to drawings. To suggest otherwise is to suggest that the term "elongated" with a drawing of a pole is indefinite because no precise dimensions are offered, or the term "roughened" with a disclosure of sandblasting is indefinite because there are other methods for roughening and other measures of roughness. The particular examples in this case, in text and in drawings, help define "finlike."

5) As the Office Action notes, the handles in Figures 9 and 10 have similar outer perimeters. It is consistent with the meaning of "finlike" that both those handles fit within that term. Indeed, the Office Action noted that Figure 10 is an example of a "solid finlike" handle. That is a further indication of what the specification conveys to the person of ordinary skill, and how that person would understand the bounds of that language.

6) It is agreed that limitations cannot be read into the claims from the specification. There is no need to do so here, because "finlike" is well-definable on its own, from its ordinary meaning. If there is any doubt, reference to the intrinsic evidence of the specification and drawings help to interpret that term. No suggestion is being made to import limitations from the specification.

7) The example in MPEP 2173.05(d) relied on in the Office Action is also distinguishable. The case relied on concerned identification of two particular substances and

then adding "or like material." Here a term with a particular meaning is not added to, but is identified with particular examples in drawings and text.

The standard for definiteness is whether one of ordinary skill will understand the bounds of the claim. The implementation of that standard is to determine whether a discernable interpretation can be made, even if that interpretation may be the subject of reasonable disagreement. "Finlike" has an ordinary meaning, and it is linked to structure in the drawings and text. The term is not insolubly ambiguous, and therefore passes the test of Section 112.

Conclusion

It should be understood that the above remarks are not intended to provide an exhaustive basis for patentability or to concede any basis for the rejections in the Office Action but are simply provided to address the rejections made in the Office Action in an expedient fashion. Applicant reserves the right to later contest positions taken by the Examiner that are not specifically addressed herein. No narrowing amendments necessary to patentability have been made in this paper, and no narrowing through any remarks herein is intended or should be inferred.

Reconsideration and passage to allowance in view of the above amendments and remarks is respectfully requested.

Respectfully submitted,

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